## **AMENDMENT**

Please enter the following amendments. Deleted subject matter is indicated with strikethrough text and added subject matter is indicated with underlined text. The current listing of Claims supersedes all previous versions.

## **IN THE CLAIMS**:

- 1. (Currently Amended) An implantable or insertable medical device comprising a release region, said release region comprising (a) a polymeric carrier comprising a <a href="https://hydrophobic.nlm.nih.good.">hydrophobic.</a> first polymer and (b) drug loaded nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising: silicate particles comprising a layered silicate material; and a <a href="hydrophilic.">hydrophilic.</a> first therapeutic agent; and a hydrophilic second polymer, wherein the first therapeutic agent and hydrophilic second polymer are is-structurally associated with the silicate particles in that the first therapeutic agent and hydrophilic second polymer occupy occupies spaces between adjacent layers of the silicate material of each silicate particle to form a depot for the first therapeutic agent.
- 2. (Canceled) The medical device of claim 1, wherein said first therapeutic agent is a hydrophilic therapeutic agent and said first polymer is a hydrophobic polymer.
- 3. (Currently Amended) The medical device of claim 2 1, wherein said medical device is a vascular medical device, wherein said first therapeutic agent is halofuginone HBr, and wherein said first polymer is a polyolefin-polyvinylaromatic block copolymer.
- 4. (Canceled) The medical device of claim 1, wherein said first therapeutic agent is a hydrophobic therapeutic agent and said first polymer is a hydrophilic polymer.
- 5. (Canceled) The medical device of claim 1, further comprising a second polymer.

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6. (Canceled) The medical device of claim 5, wherein said polymeric carrier further comprises

said second polymer.

7. (Canceled) The medical device of claim 5, wherein said nanoparticles further comprise said

second polymer.

8. (Canceled) The medical device of claim 7, wherein said second polymer is hydrophobic and

said first polymer is hydrophilic.

9. (Canceled) The medical device of claim 7, wherein said second polymer is hydrophilic and said

first polymer is hydrophobic.

10. (Withdrawn and Currently Amended) The medical device of claim 9 6, wherein said medical

article is a vascular medical device, wherein said first therapeutic agent is halofuginone HBr,

wherein said first polymer is a polyolefin-polyvinylaromatic block copolymer, and wherein said

second polymer is a hydrophilic polymer selected from hyaluronic acid, collagen, heparin,

chrondroitin sulfate, phosphoro choline, dextran, and polyethylene oxide.

11. (Withdrawn) The medical device of claim 1, wherein said polymeric carrier further comprises

said first therapeutic agent.

12. (Withdrawn) The medical device of claim 1, further comprising a second therapeutic agent.

13. (Withdrawn) The medical device of claim 12, wherein said polymeric carrier further

comprises said second therapeutic agent.

14. (Withdrawn) The medical device of claim 13, wherein said first therapeutic agent is

hydrophilic and said second therapeutic agents is hydrophobic.

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15. (Withdrawn) The medical device of claim 12, wherein said nanoparticles further comprise

said second therapeutic agent.

16. (Withdrawn) The medical device of claim 15, wherein said first and second therapeutic agents

are hydrophilic.

17. (Previously Presented) The medical device of claim 1, wherein said release region is disposed

over at least a portion of a medical article substrate.

18. Canceled.

19. (Currently Amended) The medical device of claim 48 1, wherein said device is adapted for

implantation or insertion into the coronary or peripheral vasculature.

20. (Withdrawn) The medical device of claim 19, wherein said device is adapted for implantation

or insertion into the esophagus, trachea, colon, biliary tract, urinary tract, prostate or brain.

21. (Previously Presented) The medical device of claim 19, wherein said device is selected from a

catheter, a guide wire, a balloon, a filter, a stent, a stent graft, a vascular graft, a vascular patch, a

shunt, an electrode, a heart valve, a circulation pump, and an intraluminal paving system.

22. (Previously Presented) The medical device of claim 19, wherein said therapeutic agent is

selected from an anti-thrombotic agent, an anti-proliferative agent, an anti-inflammatory agent, an

anti-migratory agent, an agent affecting extracellular matrix production and organization, an

antineoplastic agent, an anti-mitotic agent, an anesthetic agent, an anti-coagulant, a vascular cell

growth promoter, a vascular cell growth inhibitor, a cholesterol-lowering agent, a vasodilating

agent, and an agent that interferes with endogenous vasoactive mechanisms.

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23. (Previously Presented) The medical device of claim 1, wherein said layered silicate material

comprises synthetic or naturally occurring smectite.

24. (Withdrawn) The medical device of claim 1, wherein said layered silicate material comprises a

natural or synthetic silicate material selected from bentonite, aliettite, vermiculite, swinefordite,

montmorillonite, yakhontovite, nontronite, beidellite, volkonskoite, stevensite, hectorite, saponite,

laponite, sauconite, magadiite, kenyaite and ledikite.

25. (Previously Presented) A method of releasing a therapeutic agent to a patient comprising: (a)

providing the medical device of claim 1; and (b) contacting said medical article with a patient.

26. (Withdrawn) A method of providing the medical device of claim 1 comprising:

providing a release-region-forming fluid comprising (a) said first polymer species and (b)

said drug loaded nanoparticles; and

applying said release-region-forming fluid to a medical article substrate or to a releasable

template.

27. (Previously Presented) The medical device of claim 1 wherein the silicate particles have a

maximum cross-sectional length between 30 to 500 nm and spacing between the adjacent layers

within the silicate particles is in the range of 5-20Å.

28. (Currently Amended) The medical device of claim 2 1 wherein said hydrophobic polymer is

selected from the group consisting of olefin polymers and copolymers, styrene polymers and

copolymers, halogenated hydrocarbon polymers and copolymers, vinyl polymers and copolymers,

polymers and copolymers of acrylic acid esters, polymers and copolymers of methacrylic acid

esters, polycarbonates, polyimides, polyetheretherkeones polyetheretherketones, polyamides,

polyvinylaceteates, polysulfones, polyethersulfones, polyesters, polyurethanes and siloxane-

urethane copolymers, and polyorganosiloxanes.

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